



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/764,371	01/23/2004	Arnold Stan Lippa	10596-018-999	9973
20583	7590	11/10/2005	EXAMINER	
JONES DAY 222 EAST 41ST ST NEW YORK, NY 10017			SOLOLA, TAOFIQ A	
			ART UNIT	PAPER NUMBER
			1626	

DATE MAILED: 11/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/764,371

Applicant(s)

LIPPA ET AL.

Examiner

Taofiq A. Solola

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 15 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 45-48 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 45-48 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>4</u> . | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1626

Claims 45-48 are pending in this application.

Claims 1-44, 49-56 are canceled.

Request for Continued Examination

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.117(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/15/05 has been entered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 45-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beer et al., US 6,204,284 B1.

Applicant claims a method of using the instant compound, in its (-) isomeric form substantially free of the corresponding enantiomers, for treating addictive disorder.

Determination of the scope and content of the prior art (MPEP §2141.01)

Beer et al., teach a method of using the racemic mixture of the instant compound for treating addictive disorder.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

Art Unit: 1626

The difference between the instant invention and that of Beer et al., is that applicant uses the (-) isomer substantially free of the corresponding (+) isomer instead of racemic mixture by Beer et al.

Finding of prima facie obviousness--rational and motivation (MPEP §2142.2413)

However, the racemic mixture of Beer et al., include the (-) isomer and the phraseology "substantially free" implies the instant compound is not 100 % (-) isomers: "contains no more than 5 % w/w the . . . (+) isomer." The compound of Beer et al., and the instant compound have both isomers except in degrees. Therefore, the instant invention is prima facie obvious from the teaching of Beer et al. One of ordinary skill in the art would have known to use the (-) isomer at the time the invention was made. The motivation is from a well-established principle that an isomer is often more reactive than the corresponding isomer or the racemate. *In re Adamson*, 125 USPQ 233 (1960). Therefore, one of ordinary skill in the art wanting to know the more active isomer would have separated the isomers. Also, the selection of an isomer among its racemic mixture is prima facie obvious. *In re Lemin*, 141 USPQ 814 (1964).

Applicant's arguments filed 9/15/05 have been fully considered but they are not persuasive. Applicant contends that the Office provides no evidence of how much of each isomer is present in the racemic mixture of Beer et al., and "the Office continues to minimize the difference between" the instant mixture and that of Beer et al. This is not persuasive because the amount of the isomers in the mixture of Beer et al., is not the basis of the rejection. The important issue is that applicant's work is obvious from the teaching of Beer et al for reasons set forth above. Applicant further argues that the Office issued US 6,569,887, directed to the instant isomer and US 6,716,868, directed to method of using the instant isomer for treating any

Art Unit: 1626

disorder due to inhibition of dopamine reuptake (reach-through claim). This is not persuasive because each application is examined on its merit.

Double Patenting Rejection

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 45-48 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No. 6,716,868. Although the conflicting claims are not identical, they are not patentably distinct from each other because in US '868, applicant claims a method of using the instant compound for treating a disorder alleviated by inhibition of dopamine reuptake. In US '868, column 7, lines 25-26, the disorders include "attention deficit, depression, obesity, Parkinson's disease, tic disorders and addictive disorders." In the instant application, applicant claims method of using the same compound for treating an addictive disorder. However, the selection of one/some among many is *prima facie* obvious. *In re Lemin*, 141 USPQ 814 (1964). One of ordinary skill in the art would have known

Art Unit: 1626

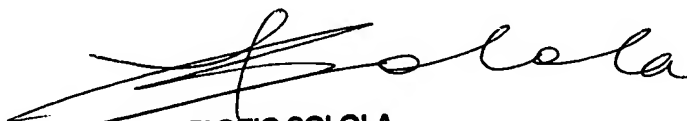
to select any of the disorders listed in column 7, lines 25-27 of US '868 at the time the invention was made.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taofiq A. Solola, PhD. JD., whose telephone number is (571) 272-0709.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph McKane, can be reached on (571) 272-0699. The fax phone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

A handwritten signature in black ink, appearing to read 'Solola', with a stylized flourish at the beginning.

**TAOFIQ SOLOLA
PRIMARY EXAMINER**

Group 1626

November 7, 2005